Remarks

Applicants have carefully considered this Application in connection with the Examiner's Action and respectfully request reconsideration of this Application in view of the following remarks.

Claim 1 has been amended to include the limitations of Claim 2. As a result, Claim 2 has been cancelled. Claim 3 has been amended to correct a typographical error. Support for the amendment to Claim 1 can be found, at least in part, on page 1 of the Specification.

I. Provisional Rejections

A. Provisional rejection for nonstatutory obviousness-type double patenting over claims 3, 5 and 6 of copending U.S. Patent Application number 11/823310 in view of Patani et al.

The Examiner rejected Claims 1, 2, 4 and 5 on the ground of nonstatutory obviousness-type double patenting over claims 3, 5 and 6 of copending U.S. Patent Application number 11/823310 in view of Patani et al. The Examiner states that although the conflicting claims are not identical, they are not patentably distinct from each other because a genus of compounds and compositions containing them overlap in subject matter with the instant genus of compounds and compositions differing structurally only in the trivalent substitution in the 4 position within the pyridine ring of the compound. (See Office Action, last full paragraph on page 2). The copending compounds have a –N= at the 4 position whereas the instant compounds have a –C= at the 4 position. (See Office Action, second full paragraph on page 3.) The Examiner cites Patani et al as teaching that a classical biosteric replacement is –C= with –N=. (See Office Action, second full paragraph on page 3.)

As a result of the amendment to Claim 1, all of the claimed compounds are radiolabeled compounds. The copending application discloses that the claimed compounds are mGluR5 antagonists and are effective in the treatment of pruritic

conditions. The copending application does not disclose any specific radiolabeled compounds. In addition, in view of the copending application and Patani et al, one of ordinary skill in the art would not have been motivated to radiolabel the compounds of formula I of the instant application. As a result, the Applicants' inventions claimed in claims 1, 2, 4 and 5 would not be obvious in view of the copending application and Patani et al. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

B. Provisional rejection of Claims 1, 2, 4 and 5 under 35 U.S.C. §103(a) for obviousness over copending U.S. Patent Application number 11/823310 in view of Patani et al.

The Examiner provisionally rejected Claims 1, 2, 4 and 5 under 35 U.S.C. §103(a) for obviousness over copending U.S. Patent Application number 11/823310 in view of Patani et al. The examiner stated that the copending application has an earlier effective US filing date and would constitute prior art under 35 U.S.C. §103(e) if published or patented. (See Office Action, page 4, second full paragraph.) The Examiner stated that this provisional application might be overcome by showing that the copending application is disqualified under 35 U.S.C. §103(c) as prior art in a rejection under 35 U.S.C. §103(a). (See Office Action, page 4, last sentence.)

In order to be disqualified as prior art under 35 U.S.C. §103(c), the claimed invention must be commonly owned or subject to an obligation of assignment to the same person at the time the claimed invention was made. In this case, both the inventors of the copending application and the Applicants were under an obligation of assignment to Novartis AG at the time the Applicants' claimed inventions were made. As a result, the copending application is disqualified as prior art under 35 U.S.C. §103(c) and the rejection has been overcome. Accordingly, withdrawal of the rejection is respectfully requested.

II. Rejections under 35 U.S.C. §112.

A. Rejection of Claims 1-6 under 35 U.S.C. §112, first paragraph.

The Examiner rejected Claims 1-6 under 35 U.S.C. §112, first paragraph, stating that the Specification was only enabling for the compounds of formula I that are 3-(6-methyl-pyridine-2-ylethynyl)-cyclohex-2-enone O-[C-methyl]-oxime on the basis that none of the working examples involves the use of any other claimed compounds in the binding assay or in the brain study and that undue experimentation would be required to practice Applicants' inventions. (See Office Actions, pages 6 -10.) The Examiner sets forth factors included in the factors to be considered in determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". (See Office Action, page 6, citing In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed Cir. 1988) and quoting the factors as they appear in MPEP Section 2164.01(a).)

When those factors are considered, it is clear that Claims 1-6 are enabled and that undue experimentation would not be required to practice the Applicants' inventions.

With respect to the breadth of the claims, Claim 1, as amended, only covers 14 compounds and free base and acid addition salt forms thereof, and does not cover a "myriad of compounds" as stated by the Examiner. (See Office Action, the last sentence on page 7. Even before Claim 1 was amended, the number of compounds. encompassed by Claim 1 was still very limited and was not a myriad of compounds.) Since the remaining claims all refer to a compound of formula I, all of the claims are narrow claims.

With respect to nature of the claimed inventions, they are limited in scope to a limited number of compounds and a process for the production of those compounds, and the claimed compounds are useful as a marker for neuroimaging (see Claim 4) and for labeling brain and peripheral nervous system structures involving mGlu5 receptors (see Claims 5 and 6).

With respect to the prior art, one skilled in the art with the benefit of the Applicants' disclosure would understand from the prior art how to make and use the claimed inventions.

With respect to the level of predictability in the art, the examiner contends that physiological activity is well known to be unpredictable. (See Office Action, page 9.) However, in this case, there are a limited number of substituents that are isotopes in the radiolabeling field.

With respect to the amount of direction provided by the inventors, the Specification provides specific teachings and examples about the synthesis of the claimed compounds as well as their use.

With respect to the existence of working examples, there are working examples on how to make more than just 3-(6-methyl-pyridine-2-ylethynyl)-cyclohex-2-enone O-[^{11}C -methyl]-oxime. There are examples showing how to make three other claimed compounds. Simply because there are only examples in the Specification of 3-(6-methyl-pyridine-2-ylethynyl)-cyclohex-2-enone O-[^{11}C -methyl]-oxime used in a binding assay and in rats does not mean that there is no enablement with respect to any other claimed compound or its claimed use, especially due to the structural similarity of the limited number of claimed compounds. It appears that the Examiner is essentially making this factor the determining factor with respect to enablement. However as stated in the MPEP, "The presence of only one working example should never be the sole reason for rejecting claims as being broader than the enabling disclosure, even though it is a factor to be considered along with all the other factors." (See MPEP Section 2164.02). In this case, the working examples are enabling for all of the claimed inventions, especially when the other factors are considered.

With respect to the quantity of experimentation needed to make and use the inventions based on the content of the disclosure in the Specification, the quantity of experimentation would be minimal in view of the details in the examples on how to make four of the claimed compounds and how to use one of them. Due to the structural similarity of the claimed compounds, the details in the examples, and the knowledge of one skilled in the art, the amount of experimentation that would be needed would be minimal and would not arise to the level of "undue experimentation".

When these factors are considered, it is clear that this is not the case where there are thousands or hundreds of thousands of claimed compounds with numerous claimed uses and proportionally few working examples in view of the broad scope of the claimed compounds and uses. Rather, it is a case where there are a very limited number of structurally similar compounds with narrowly claimed uses, and ample examples to teach one skilled in the art how to make and use the claimed inventions. In other words, all of the claimed inventions have clearly been enabled by the Applicants and undue experimentation would not be required to make or use any of the claimed inventions. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

B. Rejection of Claim 6 under 35 U.S.C. §112, second paragraph.

The Examiner rejected Claim 6 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention due to there being no reference to the host in which the labeling is taking place. The claim specifies the specific tissue in which the labeling is taking place and therefore is not indefinite. In other words, the specificity with respect to the tissue means that the host does not need to be specified. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

III. Conclusion

In view of the foregoing, Claims 1-6 are in condition for allowance, and Applicants earnestly solicit a Notice of Allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this Application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration to this Reply is respectfully requested.

Respectfully submitted,

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